

### **REMARKS**

Claims 36-42, 44-47, and 49-51 are pending in this application. No claims have been allowed. Claims 36-41 and 44 have been withdrawn. The Examiner rejected claims 42 and 46-51 on several grounds, including: 35 USC § 112, first paragraph, the written description requirement; 35 USC § 112, first paragraph, the enablement requirement; 35 USC § 112, second paragraph, failure to particularly point out and distinctly claim subject matter which applicant regards as his invention; and 35 USC § 103, obviousness. The Examiner also objected to claim 1 [sic, claim 42] because of the term “culture matrix” and to claim 51 for a spelling error to the term “Coriolis forces.” The Examiner also denied priority of the present application to the related prior applications (provisional application 60/043205 and the parent non-provisional application serial numbers 09/056,363 and 09/532,001) described in the Preliminary Amendment filed December 11, 2003.

In this Response, the Applicants have amended the Specification at several paragraphs to correct minor spelling and typographical errors, including the spelling error noted by the Examiner to the term “Coriolis forces”. The Applicants have also substituted the order of the reference to the Related Applications for priority such that they now appear as the first sentence of the specification following the title. No new matter within the prohibition of 35 U.S.C. § 132 has been added.

Further, the Applicants have amended independent claim 42 to include the limitation of a “cell culture matrix” as suggested by the Examiner and have amended claim 51 to correct the spelling error to the term “Coriolis forces”. Additionally, the Applicants have amended independent claim 42 to remove the term “renal stem cells” and inserted the term “human embryonic renal cells” in lieu thereof. The Applicant kindly requests reconsideration and allowance of the pending claims for the reasons detailed below.

#### **A. Priority**

The Examiner declined to grant previously presented independent claim 42 priority to any of the parent applications previously filed and referenced by this related patent application. Apparently the Examiner based this decision in part on the cross-

reference not being found in the first sentence of the specification. The Examiner also denied priority because the prior filed parent applications did not “teach culture of renal stem cells in any capacitation.”

In view of these remarks, the Applicants have amended the specification such that the references to the earlier filed applications appear as the first sentence of the specification (page 1, line 1) as opposed to immediately after the paragraph with the heading entitled “Origin of the Invention” (page 1, line 14) given in the Preliminary Amendment filed on December 11, 2003. The Applicants have also amended claim 42 to remove the term “renal stem cells” and instead use the term “human embryonic renal cells”. The Applicants submit that the term “human embryonic renal cells” appears in the specification at page 22, lines 2 and 12, page 23, line 1, and page 24, line 28. The Applicants also note that this term appears in the text of the provisional application, specifically pages 73-74.

The Applicants note that 35 USC § 119(c)(1) states:

(e)(1)An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application.

Further, the Applicants note that 35 USC § 120 provides:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

The Applicants respectfully submit that the present application as amended contains the specific reference to the earlier filed applications as given in 35 USC §§ 119(e)(1) and 120. Specifically, the application as now amended provides:

The present application is a continuation of U.S. Application Serial No. 09/532,001, filed March 21, 2000, now U.S. Patent No. 6,946,246, which is a divisional of U.S. Application No. 09/056,363, filed April 7, 1998, now U.S. Patent No. 6,730,498, which claims the benefit of provisional U.S. Application Serial No. 60/043,205, filed April 8, 1997.

Accordingly, the Applicants kindly request the Examiner grant the benefit of the earlier filing date of the parent applications and the corresponding provisional application, specifically April 8, 1997, to the present application as is required under 35 USC §§ 119(e)(1) and 120.

#### **B. Rejections Under 35 USC § 112, First Paragraph**

The Examiner rejected claims 42 and 46-51 as failing to comply with the written description requirement and the enablement requirement. These rejections are primarily based on the fact that independent claim 42 was directed to a method comprising steps for isolating and culturing renal stem cells.

The Applicants wish to thank the Examiner for her thorough examination of the previous claims. The Applicants have amended independent claim 42 to remove the reference to the term “renal stem cells” and have inserted the term “human embryonic renal cells” in lieu thereof. The Applicants submit that this amended term finds support in the specification at page 22, lines 2 and 12, page 23, line 1, and page 24, line 28. Accordingly, the Applicants kindly request that the rejection of present claims 42, 46, 47, and 49-51 under 35 USC § 112, first paragraph be withdrawn.

#### **C. Rejections Under 35 USC § 112, Second Paragraph**

The Examiner rejected claims 42 and 46-51 as failing to comply with the second paragraph of 35 USC § 112. The Examiner based this rejection on several terms appearing in independent claim 42. First, the Examiner indicated that the term “active” as it appears in the preamble of claim 42 was unclear. In response thereto, the Applicants have amended the preamble of independent claim 42 to read “[a] method of producing

~~active renal epithelial cells exhibiting 1- $\alpha$ -hydroxylase activity~~ comprising...” The Applicants submit that the preamble as now written overcomes the Examiner’s prior rejection. Second, the Examiner indicated that the term “a cell culture” appearing in the second step of claim 42 is indefinite because it suggests that another cell population for co-culturing is required. In response to this comment, the Applicants have deleted the term “a cell culture” after the word “containing”. The Applicants submit this amendment addresses and removes the Examiner’s second basis of rejection under 35 USC 112, second paragraph. Third, the Examiner considered the term “substantially” to be indefinite. In response thereto, the Applicants have deleted this term from independent claim 42. Fourth, the Examiner indicated that the preamble of claim 42 did not appear to be commensurate in scope with the body of the claim. As the basis for this rejection, the Examiner explained that the preamble referred to differentiated renal cells, whereas the body of the claim referred to renal stem cells. In response to this rejection, the Applicants note that the body of independent claim 42 no longer refers to the term “renal stem cells”, which should resolve the concern of the preamble and body being commensurate in scope as articulated by the Examiner. In view of the amendments made, the Applicants submit that the preamble and body of amended claim 42 satisfy the requirements of 35 USC § 112, second paragraph, in that the amended claim particularly points out and distinctly claims the subject matter concerned. Accordingly, the Applicants kindly request that the Examiner withdraw her rejection of claims 42, 46, 47, and 49-51 under 35 USC § 112, second paragraph.

#### **D. Rejection Under 35 USC § 103**

The Examiner rejected claims 42 and 46-51 under 35 USC § 103 as being unpatentable over Humes (U.S. Patent No. 6,410,320), in view of Goodwin et al., Uemura et al., Unsworth et al., and Hammond et al. In response to this rejection, the Applicants note that this rejection depended in large part on references that were published after the filing date of the parent applications and provisional application referenced by the present application. Given that independent claim 42 no longer refers to the term “renal stem cell”, the Applicants reassert the remarks previously made regarding the entitlement to the benefit of the earlier filing dates of the parent

applications and of the provisional application and their date of priority should be given to the present application under 35 USC § 120. Such priority date (April 8, 1997) precedes the publication and the filing date of the primary reference cited by the Examiner (Humes) and the publication or filing date of three of the other four references relied upon (Uemura, Unsworth, and Hammond) by the Examiner. Accordingly, the Applicants kindly request that the Examiner withdraw her rejection of claims 42, 46, 47, and 49-51 under 35 USC § 103, considering that the amendments to the references of the earlier filed applications in the specification and to independent claim 42 have mooted the Examiner's rejection.

CONCLUSION

In view of the above Response, the Applicants submit that the pending claims in the instant application are in condition for allowance. The Applicants invite the Examiner to contact Mr. Kurt G. Hammerle, attorney for the Applicants, at 281-483-1001 to facilitate prosecution of this matter. The Applicants respectfully request an early action to this end.

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Date

Respectfully submitted,

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